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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,598	04/26/2001	H. Robert Horvitz	01997/525002	8753

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[REDACTED] EXAMINER

PARAS JR, PETER

[REDACTED] ART UNIT 1632

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Applicant No.</b>	<b>Applicant(s)</b>	
	09/843,598	HORVITZ ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Peter Paras, Jr.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 January 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-12 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 15 October 2002 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7, 9</u> | 6) <input type="checkbox"/> Other: _____                                    |

Applicant's amendment received on 4/28/02 has been entered. Claims 3-7 and 11 have been amended. New claim 12 has been added. Applicant's amendment received on 1/28/03 has been entered. Claims 1 and 2 have been amended. Claims 1-12 are pending and are under current consideration.

### ***Drawings***

The formal drawings submitted on 10/15/02 have been approved by the Examiner.

### ***Oath/Declaration***

The substitute declaration submitted by Applicants is defective as the date of the second inventor's signature is incomplete. Applicants are requested to provide a complete declaration that has been properly executed.

The following are new grounds of rejection under 35 USC § 112, 1<sup>st</sup> paragraph:

### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to methods for determining the activity range of a test compound, which modulates the uptake of serotonin by a serotonin reuptake transporter (SERT), against a secondary target comprising contacting a first nematode with a test compound and comparing the effect of the compound with the behavior of untreated second nematode.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the *invention*. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116.

The specification has disclosed *C. elegans* having a mutated mod-5 polypeptide comprising mod-5 (n822), mod-5(n823), or mod-5(n3314) mutations. The specification however has not disclosed the other nematodes encompassed within the genus of nematode expressing a mutated CeSERT polypeptide. There is no evidence on the record of a relationship between the structures of the nematode encompassed by the claims that would provide any reliable information about the structure of nematodes within the genus. There is no evidence on the record that nematodes had known structural relationships to each other; the art indicated that there is structural variation

between nematodes and CeSERT polypeptides. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which is not conventional in the art as of applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998).

In the instant case the claimed embodiments of nematode expressing a mutated CeSERT polypeptide, other than *C. elegans* having a mutated mod-5 polypeptide comprising mod-5 (n822), mod-5(n823), or mod-5(n3314) mutations encompassed within the genus of nematodes lack a written description. The specification fails to describe which nematodes fall into this genus, other than *C. elegans* having a mutated mod-5 polypeptide comprising mod-5 (n822), mod-5(n823), or mod-5(n3314) mutations. The skilled artisan cannot envision the detailed chemical structure of the encompassed nematodes, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by member of the genus of nematodes expressing a mutated CeSERT polypeptide, other than *C. elegans* having a mutated mod-5 polypeptide comprising mod-5 (n822), mod-5(n823), or mod-5(n3314) mutations. Moreover, the art has recognized that there would be structural variation among the species of the nematodes and CeSERT polypeptides encompassed within the genus. Therefore, Applicant was not in possession of the genus of nematodes expressing a mutated CeSERT polypeptide, as encompassed by the claims. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention."

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to methods for determining the activity range of a test compound, which modulates the uptake of serotonin by a serotonin reuptake transporter (SERT), against a secondary target comprising contacting a first nematode with a test compound and comparing the effect of the compound with the behavior of untreated second nematode.

The specification discusses that the invention features a method for identifying test compounds that modulate uptake of serotonin. The specification discusses that the invention features nematodes expressing mutated CeSERT polypeptides, which are used in screening methods to identify the test compounds. While the specification provides extensive teachings pertaining to the use of *C. elegans* having a mutated mod-5 polypeptide comprising mod-5 (n822), mod-5(n823), or mod-5(n3314) mutations the specification fails to provide any relevant teachings or specific guidance with regard to the use of the other nematodes expressing mutated CeSERT polypeptides embraced by the claims. Finally, the specification has failed to provide guidance that correlates a defined behavior with modulation of the uptake of serotonin by modulating the activity of a secondary target as embraced by the claims. Given the lack of guidance provided by the specification it would have required undue experimentation to practice the claimed methods with the other nematodes embraced by the claims.

While the specification has provided guidance for use of *C. elegans* having a mutated mod-5 polypeptide comprising mod-5 (n822), mod-5(n823), or mod-5(n3314) mutations for identifying test compounds that modulate the uptake of serotonin the specification has not provided relevant teachings or guidance for use of the other

nematodes embraced by the claims. The specification has contemplated that other nematodes may be used to identify such compounds. However, the specification has failed to recite which other nematodes could be used to practice the claimed methods. Moreover, the specification has failed to provide any guidance, working examples, or relevant teachings that would allow the skilled artisan to use nemtodes other than a *C. elegans* having a mutated mod-5 polypeptide comprising mod-5 (n822), mod-5(n823), or mod-5(n3314) mutations when practicing the claimed invention and the specification has not provided any correlation between use of the disclosed *C. elegans* and any other nematode in the claimed methods so that the skilled artisan could extrapolate use of the *C. elegans* to use of other nematodes. As previously stated the specification has not even identified which other nematodes could be used to practice the claimed invention. A mere statement that other nematodes exist and could be used is not sufficient to enable the breadth of the methods as directed to any nematode expressing a mutated CeSERT polypeptide. If there is no disclosure of starting material or of any conditions under which claimed process can be carried out, undue experimentation is required, and there is failure to meet enablement requirement that cannot be rectified by asserting that all disclosure related to process is within skill of art. See Genentech Inc. v. Novo Nordisk A/S 42 USPQ2d 1001, 1997. In this case the starting material that has not been disclosed is any other nematode expressing a CeSERT polypeptide embraced by the claims.

In addition, the claims embrace comparison of said defined behavior of said first nematode contacted with a test compound to the defined behavior of a second

nematode not contacted with the compound, wherein a difference in the defined behaviors indicates that a compound can modulate the uptake of serotonin by modulating a secondary target. The specification however has failed to provide guidance that correlates a defined behavior with uptake of serotonin by modulation of a secondary target. Moreover, the claims as written are broad and encompass any defined behavior and any secondary target despite the fact that the evidence of record has failed to correlate any defined behavior with serotonin uptake. The claims also do not require that the defined behaviors to be compared between the first and second nematode are the same. Finally, a C. elegans mod-5(n3314) homozygous mutant does not produce any mod-5 and therefore cannot transport any serotonin according to the specification. As such the claims do not appear to be enabled for use of the mod-5 (n3314) since it does not appear to able to transport serotonin. See the specification on pages 25-27.

Given the lack of guidance provided by the instant specification for use of the other nematodes expressing CeSERT polypeptides embraced by the claims it would have required undue experimentation for one skilled in the art to make and/or use the claimed invention.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the defined behavior of a second nematode" in step (c), lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Claims 2-11 depend from claim 1.

Claim 12 recites the limitation "the defined behavior of a second nematode" in step (c), lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Claims 2-11 depend from claim 12.

Claim 1 is unclear as written. The claim is directed to a method for determining the activity range of a test compound, which modulates the uptake of serotonin by a serotonin reupake transporter (SERT), against a secondary target, wherein defined behaviors of a first and second nematode are compared. The claim is unclear as written because it is not clear if the defined behaviors of the first and second nematodes are the same. Moreover it is unclear how an activity range of a test compound can be meaningfully assessed if two different defined behaviors are being compared to determine the activity range. Correction is required. Claims 2-11 depend from claim 1.

Claim 12 is unclear as written. The claim is directed to a method for identifying a test compound, capable of modulating the uptake of serotonin by a serotonin reupake

transporter (SERT), by modulating the activity of a secondary target that is not a SERT, wherein defined behaviors of a first and second nematode are compared. The claim is unclear as written because it is not clear if the defined behaviors of the first and second nematodes are the same. Moreover, it is unclear how a test compound can be identified if two different defined behaviors are being compared in order to identify the test compound. Correction is required. Claims 2-11 depend from claim 12.

Claim 1 is unclear as written. The claim is directed to a method for determining the activity range of a test compound, which modulates the uptake of serotonin by a serotonin reuptake transporter (SERT), against a secondary target. It is unclear what is meant by the phrase, "which modulates the uptake of serotonin by a serotonin reuptake transporter, against a secondary target". It is unclear how serotonin uptake can be modulated against a secondary target. Clarification is required. Claims 2-11 depend from claim 1.

### **Conclusion**

**No claim is allowed.**

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

**PETER PARAS**  
**PATENT EXAMINER**

Art Unit 1632

